K050991

JUL 15 2005

510(k) Summary
For The
ODFS Dropped Foot Stimulator

1. SPONSOR

Department of Medical Physics and Biomedical Engineering
Salisbury Heath Care NHS Trust
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ United Kingdom

Contact Person: Tina E. Lechman, NDI Medical
Telephone: 216-378-9106 ext. 101

Date Prepared: April 15, 2005

NDI Medical (US Agent)
One Chagrin Highlands
2000 Auburn Drive, Suite 320
Cleveland, OH 44122
Telephone: 216-378-9106
Fax: 216-378-9116

2. Device Name

Trade/Proprietary Name:	The ODFS Dropped Foot Stimulator
Common/Usual Name:	External Functional Neuromuscular Stimulator (FES)
Classification Name:	External Functional Neuromuscular Stimulator (FES) Powered Muscle Stimulator (NMES)
Classification Code:	Class II
Product Codes:	GZI and IPF

3. PREDICATE DEVICES

Predicate Name	Company	K Number
EMPI Focus Model 795	EMPI	K951951
WalkAide	NeuroMotion	K974514

4. DEVICE DESCRIPTION

The ODFS Dropped Foot Stimulator (ODFSIII Version 6.2) is an external functional neuromuscular stimulator. The ODFS Dropped Foot Stimulator electrically stimulates the common peroneal nerve which may produce contraction of the appropriate muscles that cause dorsiflexion of the ankle in individuals who have lost the ability to do so following neurological injury.

The device is comprised of a small belt-worn, single-channel, foot-switch controlled stimulator used with skin-surface stimulating electrodes. The surface electrodes are typically placed over the common peroneal nerve as it passes near the head of the fibula and the motor point of the tibialis anterior in the lower leg. The heel switch allows the delivery of stimulation to be triggered according to the gait of the user.

5. INTENDED USE

The ODFS Dropped Foot Stimulator is intended to provide ankle dorsiflexion in individuals with dropped foot following an upper motor neuron injury. During the swing phase of gait, the ODFS electrically stimulates muscles in the leg and ankle of partially paralyzed individuals to provide flexion of the foot and may thus improve the individual's gait. Additional benefits of Functional Electrical Stimulation (FES) may include muscle re-education, prevention/retardation of disuse atrophy, maintained or increased joint range of motion, and increased local blood flow.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Feature	ODFS	EMPI Focus Model 795	WalkAide
Waveform	Biphasic (Symmetrical and Balanced Asymmetrical)	Biphasic (Symmetrical and Balanced Asymmetrical)	Not available
Pulse Width	7 (±4) to 365(±20) µsec (patient selectable)	300 µsec	200 µsec
Frequency (Hz)	40 (±4) Hz	25, 30, 35, 45, 50, 80 Hz	25 Hz
Indications for Use	To provide ankle dorsiflexion in individuals with dropped foot following an upper motor neuron injury. During the swing phase of gait, the ODFS electrically stimulates muscles in the leg and ankle of partially paralyzed individuals to provide flexion of the foot and may thus improve the individual's gait. Additional benefits of Functional Electrical Stimulation (FES) may include muscle re-education, prevention/retardation of disuse atrophy, maintained or increased joint range of motion, and increased local blood flow.	As a TENS device: Symptomatic relief and management of chronic intractable pain; adjunctive treatment for post-surgical and post-trauma acute pain As a NMS/NMES device:. Relaxation of muscle spasm; prevention or retardation of disuse atrophy; increasing local blood circulation; muscle re-education; immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis; maintaining or increasing range of motion. As a FES device: Stimulating muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.	To address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of gait, the WalkAide electrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the patient's gait. Medical benefits of FES may include prevention/retardation of disuse atrophy, increased local blood flow, muscle re-education, and maintained or increased joint range of motion.
Accessories	Heel switch	Heel switch, Hand switch	Heel switch, Tilt sensor
Electrode Size and Shape	5.0 cm x5.0cm square = 25 cm^2	5.1cm^2	2.5cm round
	4cm x 6.4 cm oval = 20 cm^2		

7. PERFORMANCE TESTING

The ODFS system has been subjected to testing to verify that the device meets its key output specifications. All units tested met product specifications.

Testing included:

- Functional verification testing of output and operational characteristics
- IEC 60601-1 (EN 60601-1:1988 with amendments of 1991 & 1995).
- IEC 60601-2-10 (as applicable).
- ISO 60601-1-2 (as applicable).

Based on the information provided, the ODFS Dropped Foot System is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Department of Medical Physics and Biomedical Eng.
Salisbury Health Care NHS Trust
c/o Ms. Tina E. Lechman
Clinical Project Manager, US Agent
NDI Medical
One Chagrin Highlands
2000 Auburn Drive, Suite 320
Cleveland, Ohio 44122

JUL 15 2005

Re: K050991
Trade/Device Name: ODFS Dropped Foot Stimulator
Regulation Number: 21 CF 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: II
Product Code: GZI
Dated: July 8, 2005
Received: July 11, 2005

Dear Ms. Lechman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050991

Device Name: ODFS Dropped Foot Stimulator

Indications for Use:

The ODFS Dropped Foot Stimulator is intended to provide ankle dorsiflexion in individuals with dropped foot following an upper motor neuron injury. During the swing phase of gait, the ODFS electrically stimulates muscles in the leg and ankle of partially paralyzed individuals to provide flexion of the foot and may thus improve the individual's gait. Additional benefits of Functional Electrical Stimulation (FES) may include muscle re-education, prevention/retardation of disuse atrophy, maintained or increased joint range of motion, and increased local blood flow.

The ODFS is a medical device and should only be used under medical supervision for adjunctive therapy for the treatment of dropped foot following an upper motor neuron injury.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050991